TAB 5

K083874
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510(K) SUMMARY

RESPIRONICS®

JAN 26 2009

Date of Submission	19 November 2008
Manufacturing Facility Address	Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668
Official Contact	Andrew P. Zeltwanger Manager, Regulatory Affairs Respironics, Inc. 1740 Golden Mile Highway Monroeville, PA 15146 Phone: 724-387-7442 Fax: 724-387-7490 Andrew.Zeltwanger@Respironics.com
Proprietary Name	Galaxy
Common/Usual Name	Ventilatory Effort Recorder
Device Classification Name	Ventilatory Effort Recorder
Classification Reference	21 CFR 868.2375
Classification	Class II
Appropriate Classification Panel	Anesthesiology
Product Code	MNR
Predicate Devices	EB Neuro, S.p.A. Sandman Pocket (K061996)
Reason for submission	New device

Substantial Equivalence

This premarket notification submission demonstrates that the Respironics, Inc. Galaxy data recorder is substantially equivalent to the EB Neuro, S.p.A. Sandman Pocket (K061996).

The functionality of the design of the device was verified through verification testing. All tests met the required acceptance criteria. The safety of the design was assured by the completion of IEC 60601-1 and IEC 60601-1-2 testing. The Risk Traceability Matrix provided in the Risk Assessment assured that all hazards identified by the risk assessment are successfully mitigated.

Intended Use

The Galaxy is a physiological data recorder intended to collect and record data from multiple physiological channels. It is intended for use by or on the order of a physician. The Galaxy is intended for use in a supervised (hospital) or unsupervised (home) environment.

Device Description

The Galaxy is a wearable data recorder that collects and stores physiological signals. The role of the Galaxy is only to record the data. The following physiological signals may be collected and stored by the Galaxy device:

- EEG, EOG, EMG, ECG
- Nasal/oral Airflow
- Snore
- Thoracic and Abdominal Effort
- Body Position
- Pulse Oximetry, including:
    - Oxygen Saturation (SpO_2)
    - Pulse Rate
    - Plethysmograph

The recorded data is stored on a secure digital (SD) card and may be passed on to a PC for analysis and reporting of the data by a cleared host software application. The Galaxy data recorder is not in any way involved in the data management performed by the host.

Technological Characteristics / Predicate Device Comparison

Like the Sandman Pocket predicate device, the Galaxy is intended to collect physiological signals from various points on the patient's body and to record those signals. Refer to Table 5-1 for a comparison of the Galaxy to the identified predicate device.

Table 5-1: Galaxy Data Recorder Comparison to Predicate Device

Characteristic	EB Neuro, S.p.A. Sandman Pocket (K061996)	Respironics Galaxy Data Recorder
Intended Use	Intended for use in collecting and recording physiological data to be used in polysomnography and sleep disorder studies. The device is intended for pediatric through adult patient populations, and can be used in either home or hospital environments. The Sandman Pocket is not intended for use as life supporting equipment, such as a vital sign monitoring in an intensive care unit. The device does not produce alarms and is not intended as an automated apnea monitor. The Sandman Pocket is only to be used under the direction or supervision of a physician, technologist or clinician.	The Galaxy is a physiological data recorder intended to collect and record data from multiple physiological channels. It is intended for use by or on the order of a physician. The Galaxy is intended for use in a supervised (hospital) or unsupervised (home) environment.
Environment of Use	Home or Hospital	Same as K061996
FDA Device Class	Class II	Same as K061996
FDA Product Code	MNR	Same as K061996
FDA Device Type	Ventilatory Effort Recorder	Same as K061996
FDA Regulation Number	21 CFR 868.2375	Same as K061996
Simultaneous Patient Recording Capability	1 patient per unit	Same as K061996
Configuration	Wearable	Same as K061996
Portability	Portable	Same as K061996
Data Input Types	Respiratory, ECG, Neurological	Same as K061996
Maximum Number of Channels	22	20

Characteristic	EB Neuro, S.p.A. Sandman Pocket (K061996)	Respironics Galaxy Data Recorder
Channel Types Recorded	EEG EOG EMG ECG Respiratory Efforts (abdominal and thoracic) Airflow Snore Body Position Oxygen Saturation Pulse Rate Plethysmograph	Same as K061996
Pressure Therapy Device Input Channel	Stores data from Nellcor Puritan Bennett pressure therapy devices and can be used to transmit data streams from the pressure therapy device to a PC.	Stores data from Respironics pressure therapy devices.
Patient Event Marker (PEM)	Yes	Same as K061996
Sensors	FDA cleared sensors	FDA cleared sensors
Electrode Impedance Check	Yes	No
Calibration Check	Yes	No
Memory	Recording stored on internal NAND flash chip	Recording stored on removable secure digital (SD) Card
Amount of Memory Required for a Typical 8 Hour Study	28 MB	230 MB
Power	Battery powered or USB powered	Battery powered
Data Transfer for Analysis and Report Generation	Data must be transferred. Data analysis and reporting is not performed by the data recorder	Same as K061996

(End of Tab.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Respironics, Incorporated
C/O Mr Ned Devine
Responsible Third Party Official
Underwriters Laboratories, Incorporated
333 Pfingsten Road
Northbrook, Illinois 60062

JAN 2 6 2009

Re K083874
Trade/Device Name Galaxy
Regulation Number 21 CFR 868 2375
Regulation Name Breathing Frequency Monitor
Regulatory Class II
Product Code MNR
Dated January 13, 2009
Received January 15, 2009

Dear Mr Devine

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA) You may, therefore, market the device, subject to the general controls provisions of the Act The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898 In addition, FDA may publish further announcements concerning your device in the Federal Register

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807), labeling (21 CFR Part 801), good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820), and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act), 21 CFR 1000-1050 This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807 97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474 For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464 You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address
http //www fda gov/cdrh/industry/support/index html

Sincerely yours,

Anthony D Watson for
Ginette Y Michaud, M D
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Indications for Use

510(k) Number (if known): _____

Device Name: Galaxy

Indications for Use:

The Galaxy is a physiological data recorder intended to collect and record data from multiple physiological channels. It is intended for use by or on the order of a physician. The Galaxy is intended for use in a supervised (hospital) or unsupervised (home) environment.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083874